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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

IN RE MERCK & CO., INC.
VYTORIN/ZETIA SECURITIES
LITIGATION

08-CV-2177 (DMC) (JAD)

Oral Argument Requested

**REPLY MEMORANDUM OF LAW IN SUPPORT OF MERCK
DEFENDANTS' MOTION FOR SUMMARY JUDGMENT**

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Preliminary Statement

Plaintiffs do not dispute that, on January 14, 2008, Defendants issued a news release disclosing that the ENHANCE trial had failed. They also do not dispute that Merck's stock price did not decline materially for three full trading days after that disclosure. Instead, Plaintiffs seek to stave off summary judgment by arguing that the January 14 disclosure did not fully reveal the alleged fraud. The record does not support their arguments.

First, Plaintiffs argue that Merck falsely stated that it expected revenues from Vytorin® and Zetia® to grow in 2007 and 2008. This argument is based on an internal, non-public business plan that the Merck/Schering-Plough Pharmaceuticals joint venture ("JV") created in 2006, which [REDACTED]

[REDACTED]

[REDACTED] (Pl. Br. 3.)

What Plaintiffs fail to mention is that the very document they rely on

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Second, Plaintiffs argue that the January 14 news release was only a partial disclosure of the alleged fraud because Merck did not disclose the "full

results” of the ENHANCE trial, which ultimately showed not only that the trial had failed, but that it had not worked in any patient subgroup or secondary endpoint. The problem with this argument is that Plaintiffs have not come forward with evidence that Defendants knew this information when issuing their news release on January 14, 2008. In short, Plaintiffs have confused disclosure of the information Merck allegedly withheld – that the trial would fail – with the publication of detailed analyses of the ENHANCE data created after the trial’s failure had been disclosed. Only the former can support a fraud claim.

Finally, Plaintiffs argue that the January 14 disclosure should be disregarded because Defendants encouraged the medical community to withhold judgment until the “full results” of the trial were released in March. However, none of Defendants’ comments undermined the notion that the trial had failed.

For these reasons, those set forth in our opening brief, and the other reasons provided below, Defendants’ motion for summary judgment should be granted and the Complaint should be dismissed with prejudice.

Argument

I.

DEFENDANTS ARE ENTITLED TO SUMMARY JUDGMENT BECAUSE MERCK’S STOCK PRICE DID NOT DECLINE MATERIALLY WHEN IT DISCLOSED THAT THE ENHANCE TRIAL HAD FAILED

Plaintiffs concede that Defendants issued a news release on the morning of January 14, 2008, disclosing that the ENHANCE trial had failed. (Affidavit of Andrew G. Gordon, sworn to March 1, 2012 (“Gordon Aff.”), Ex. 1 ¶¶ 13, 218-22.) Plaintiffs further state that the January 14 release “shocked the

market” by disclosing the “horrible” result that Vytorin “offered no real benefit to users” because it failed to “reduce the buildup of arterial plaque any more than less expensive generic simvastatin alone.” (Gordon Aff., Ex. 1 ¶¶ 13, 218; Ex. 2 ¶ 84.) Plaintiffs cite news articles published on January 14 and 15, 2008 in which prominent physicians told the press that Vytorin “just doesn’t work,” and that the trial was “as bad a result for the drug as anybody could have feared.” (Gordon Aff., Exs. 26-28.) Plaintiffs further concede that Merck’s stock and options prices did not decline materially in response to this news on January 14, 15, or 16, 2008. (Pl. Local Rule 56.1 Resp., ¶¶ 28-31; Gordon Aff., Ex. 2 ¶¶ 83, 86, 89; Ex. 3 at 193-95, 200; Ex. 32.)

Because Merck’s stock and options traded in an efficient market (Pl. Local Rule 56.1 Resp., ¶ 27), Plaintiffs cannot show that the information Defendants allegedly withheld – that the ENHANCE trial had failed – was material. And, given the lack of stock price impact upon disclosure of the failure of the ENHANCE trial, Plaintiffs also cannot show loss causation or establish a presumption of reliance for the putative class. (Def. Br. 16-21.)¹

¹ On the last page of their brief, Plaintiffs speculate that the lack of a material price decline on January 14 might be explained by the disclosure that a Vioxx settlement appeared to be going forward. (Pl. Br. 40.) This, however, was not new news on January 14. (Gordon Aff., Ex. 31 at 2 n.3.) As Plaintiffs’ expert acknowledged, *The Wall Street Journal* had reported on January 10, 2008 that it was “likely that enough plaintiffs would sign on to meet the 85% threshold for the settlement to move forward.” (Gordon Aff., Ex. 2 ¶¶ 114, 116.) Given the efficient securities market for Merck’s shares, this information was reflected in Merck’s stock price before January 14. See *In re Merck & Co., Inc. Sec. Litig.*, 432 F.3d 261, 274 (3d Cir. 2005) (Third Circuit’s “stock-price test for

Faced with these undisputed facts, Plaintiffs argue that the January 14 news release did not disclose the entire alleged fraud. Those arguments should not survive summary judgment.

II.

DEFENDANTS' STATEMENTS ABOUT THE ANTICIPATED GROWTH OF VYTORIN AND ZETIA SALES WERE TRUE

In an effort to escape the consequences of the January 14 news release, Plaintiffs argue that Defendants not only delayed disclosing that the ENHANCE trial had failed, but that they also made misleading statements “concerning Vytorin’s and Zetia’s continued growth and prospects” for 2007 and 2008. (Pl. Br. 9.) Plaintiffs contend that these statements were misleading because

[REDACTED]

[REDACTED]

[REDACTED] (Pl. Br. 7.)

This argument is based on [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] (*Id.*, citing Pl. SOF ¶¶ 42, 58; Declaration of Daniel L. Berger in Opposition to Motion for Summary Judgment, dated April 9, 2012 (“Berger Decl.”), Ex. 37 at -55683 and -715; Ex. 41 at -3290, -98; Ex. 42 at -42625

materiality” in an efficient market holds that “information important to reasonable investors . . . is immediately incorporated into stock prices”).

and -40-41.) [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] (Berger Decl., Ex. 37 at -55715 and -683.)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] (*Id.*)²

²

[REDACTED]

In short, Plaintiffs' own evidence shows that Merck's statements about anticipated JV sales conveyed what the company genuinely believed. Merck

[REDACTED]

But what Merck did tell the public was correct under either scenario. Merck did "plan to expand the success of Zetia and Vytorin' in 2007," and it did "expect[] to increase in 2007 based on the continued growth of Zetia and Vytorin," and it did expect to "further extend the success of Zetia and Vytorin," and it did expect "the income contribution related to [MSP] . . . to increase in 2008 based on the continued growth of Zetia and Vytorin." (Pl. Br. 9-10.) Those statements were not false.

Plaintiffs also challenge a July 2007 statement that Vytorin and Zetia posted "combined global sales of \$1.3 billion, an increase of 30% compared to the second quarter of 2006." (Pl. Br. 9.) But, as Plaintiffs themselves note, Vytorin and Zetia sales grew from \$3.9 billion in 2006, to \$5.2 billion in 2007 – an increase of \$1.3 billion (or 33.3%) – and Merck met its 2007 guidance. (Pl. Br. 6, 32.)

[REDACTED] Prior to the November 2009 merger with Schering-Plough, Merck was only one-half of the Joint Venture. Accordingly, [REDACTED]

[REDACTED]

[REDACTED] (<http://www.merck.com/investors/financials/form-10-k-2011.pdf> at 41.) [REDACTED]

Finally, Plaintiffs have not shown that Merck uttered a false statement regarding the equity income it expected from affiliates. Plaintiffs focus on full-year 2008 guidance given on December 4, 2007 and reaffirmed on January 30, 2008, in which Merck projected \$3 to \$3.3 billion in 2008 “equity income from affiliates,” of which the JV was one component. (Pl. Br. 2.) Plaintiffs claim that this projection was overstated because, three months later, on April 21, 2008, Merck reduced its guidance by \$700 million. (Pl. SOF ¶ 241; Berger Decl., Ex. 238 at -39898-99.)

This argument fails for at least two reasons. First, Plaintiffs have not come forward with evidence showing that Merck did not believe its 2008 guidance at the time it was made. *See, e.g., In re Donald J. Trump Casino Sec. Litig.*, 7 F.3d 357, 368-69 (3d Cir. 1993) (soft information, such as projections, actionable only “if the speaker does not genuinely and reasonably believe them”).

Second, there is no evidence that a correction of Merck’s full-year 2008 guidance caused investor losses, as required by *Dura*. Plaintiffs concede that when Merck reduced its guidance on April 21, 2008, its stock price did not drop. (Pl. Br. 38.) Although Plaintiffs urge the Court to ignore April 21 and focus instead on Merck’s stock price decline on March 31, they do not claim that any statement was made about Merck’s equity income on that day. Nor did Plaintiffs’ expert opine that the full-year 2008 equity income guidance was corrected on March 31. (Gordon Aff., Ex. 2.)

III.

DISCLOSURES MADE AFTER JANUARY 14, 2008 DO NOT WITHSTAND SUMMARY JUDGMENT

Unable to show a material loss when Merck disclosed the failure of the ENHANCE trial on January 14, 2008, Plaintiffs argue that they are entitled to damages for stock drops on January 17, January 29, and March 31, 2008.

Plaintiffs contend that the information released on those days, and the consequent stock drops, were “foreseeable consequences” of the delayed disclosure of the ENHANCE results.

The Third Circuit has not endorsed Plaintiffs’ approach to loss causation. It is not enough to ask “whether or not the loss was simply foreseeable.” *Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 181 n.24 (3d Cir. 2001); *see Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 343 (2005) (“To ‘touch upon’ a loss is not to *cause* a loss, and it is the latter that the law requires.”). Thus, the Third Circuit requires plaintiffs to prove that the “very facts” about which the defendant lied caused the injuries claimed. *See McCabe v. Ernst & Young, LLP*, 494 F.3d 418, 425-29 (3d Cir. 2007); *Berkeley Inv. Grp., Ltd. v. Colkitt*, 455 F.3d 195, 222 (3d Cir. 2006). It is “‘the exposure of the falsity of the fraudulent representation [to the market] that is the critical component of loss causation.’” *In re DVI, Inc. Sec. Litig.*, 03-cv-5336, 2010 WL 3522090, at *11 (E.D. Pa. Sept. 3, 2010) (citation omitted); *see McKowan Lowe & Co., Ltd. v. Jasmine, Ltd.*, 231 F. App’x 216, 218 (3d Cir. 2007) (loss causation requires stock drop to be caused by revelation of the “truth that was allegedly concealed”).

Here, the disclosures of January 17, January 29, and March 30 did not expose the alleged fraud. That had already happened on January 14, 2008.

A. The Events Of January 17, 2008 Do Not Show Loss Causation

Plaintiffs point to two disclosures on January 17. First, they note that Congress announced that it had expanded its investigation into Vytorin by raising questions about Merck's advertising campaign for the drug. That announcement cannot be a "corrective disclosure" because it did not disclose a new fact about the fraud Plaintiffs allege – *i.e.*, Defendants' alleged delay of the ENHANCE trial. *See In re Omnicom Grp., Inc. Sec. Litig.*, 597 F.3d 501, 511-12 (2d Cir. 2010) (corrective disclosure requires a new "hard fact"); *In re Tellium, Inc. Sec. Litig.*, 02-cv-5878, 2005 WL 2090254, at *4 (D.N.J. Aug. 26, 2005) ("*Dura* itself makes clear that loss causation is not pled upon allegations of drops in stock price following an announcement of bad news that does not disclose the fraud.").³

Plaintiffs also argue that "early prescription tracking . . . showed that Vytorin and Zetia prescriptions were beginning to decline." (Pl. Br. 15.) This, too, is not a corrective disclosure because it did not reveal the allegedly withheld ENHANCE results.

³ In their moving brief, Defendants cited cases holding that the opening of a governmental investigation is not a corrective disclosure where, as here, the investigation did not reveal any new information about the alleged fraud. (Def. Br. 26-28.) Plaintiffs responded with cases where, unlike here, the announcement was the first indication to the public of the problem at issue, and actually revealed the alleged fraud. (Pl. Br. 31-32.) Plaintiffs' sole citation from this District, *In re Bradley Pharm., Inc. Sec. Litig.*, 421 F. Supp. 2d 822 (D.N.J. 2006), involved an SEC investigation that provided the first indication to the public of the accounting problems in question.

In addition, the prescription data was disclosed to the market in a UBS analyst report that was “issued after the market close on January 17, 2008.” (Gordon Aff., Ex. 2 ¶ 97.) Plaintiffs’ expert was unable to find any public report of Vytorin prescription data issued before the market close on January 17. (Gordon Aff., Ex. 2 ¶ 98; Ex. 3 at 223-24.) The most he could say was that the prescription data “could have been available for analysis during the day on January 17, 2008.” (Gordon Aff., Ex. 2 ¶ 98.) That is not enough to allow this claim to go forward. *See Lujan v. Nat’l Wildlife Fed’n*, 497 U.S. 871, 888 (1990) (the object of Rule 56 is “not to replace conclusory allegations of the complaint . . . with conclusory allegations of an affidavit”); *In re Ikon Office Solutions, Inc. Sec. Litig.*, 277 F.3d 658, 668 n.9 (3d Cir. 2002) (warning against reliance on mere allegations at summary judgment).⁴

B. The Events Of January 29, 2008 Do Not Show Loss Causation

Plaintiffs contend that a decline in Merck’s stock price on January 29, 2008 shows loss causation because it followed a Dow Jones report that Vytorin and Zetia prescriptions had continued to fall in the U.S., and a Merrill Lynch analyst report that lowered predictions for Vytorin sales in 2008-09. (Pl. Br. 16; Gordon

⁴ Plaintiffs quote a slide from an internal draft presentation for the JV board to argue that Merck’s stock traded down on January 17-18, 2008 because [REDACTED] (Berger Decl., Ex. 175 at -152411; Pl. Br. 15, 30.) But the initial prescription data was disclosed after-hours on January 17, and there is no evidence that Merck’s stock price suffered a material decline on January 18, 2008. (Gordon Aff., Ex. 2 ¶ 98; Ex. 3 at 223-24; Ex. 25 at 22.)

Aff., Ex. 2 ¶¶ 122-27; Ex. 3 at 301, 304-05; Ex. 40.)⁵ This argument is deficient for the same reasons as the alleged disclosures on January 17. “Noticeably absent is any assertion that any wrongdoing was disclosed to the market.” *Nat’l Junior Baseball League v. Pharmanet Dev. Grp., Inc.*, 720 F. Supp. 2d 517, 561 (D.N.J. 2010).⁶

C. The Events Of March 30, 2008 Do Not Show Loss Causation

Finally, Plaintiffs seek damages for Merck’s stock price decline on March 31, 2008, the day after the ENHANCE study was published in the *New England Journal of Medicine* (“NEJM”) and discussed at the ACC conference. Plaintiffs argue that this was the first time that data quality, subgroup and

⁵ Plaintiffs’ economic expert did not opine that the Dow Jones prescription information caused losses on January 29. Presumably because that information had been reported days earlier, Dr. Jarrell attributed the loss on January 29 solely to the Merrill Lynch analyst report. (Gordon Aff., Ex. 2 ¶¶ 121-130.)

⁶ See also *Katyle v. Penn Nat’l Gaming, Inc.*, 637 F.3d 462, 475-76 (4th Cir. 2011) (analyst reports not corrective where they do not “reveal to the market the alleged fraudulent nature of [defendant’s] practices”); *Lentell v. Merrill Lynch & Co., Inc.*, 396 F.3d 161, 175 n.4 (2d Cir. 2005) (Merrill Lynch analyst downgrades not “corrective disclosures” because they did “not reveal to the market the falsity of the prior recommendations”); *Janbay v. Canadian Solar, Inc.*, 10-cv-4430, 2012 WL 1080306, at *16 (S.D.N.Y. March 30, 2012) (“the raising of questions and speculation by analysts and commentators does not reveal any ‘truth’ about an alleged fraud as required by *Dura*”); *In re DVI, Inc. Sec. Litig.*, 03-cv-5336, 2010 WL 3522090, at *23-24 (E.D. Pa. Sept. 3, 2010) (S&P analyst downgrade did not “qualify as a corrective disclosure” because “no reasonable jury could find that these disclosures revealed to the market new information about the falsity of Defendant’s alleged misstatements”).

secondary endpoint statistics were reported, and the first time physicians could appreciate the “clinical significance” of the ENHANCE trial.

This argument must fail because it confuses disclosure of the details of the ENHANCE trial with disclosure of the alleged fraud. Even if new statistical analyses of the trial data were reported on March 30, 2008, Plaintiffs have not presented evidence that Defendants knew this information on January 14, 2008. Instead, Plaintiffs claim that “by December 6, 2006, the Merck Defendants knew that ENHANCE failed – *i.e.*, Vytorin was no better than Zocor, and the IMT of Vytorin-treated patients had not regressed, but was actually worse.” (Pl. Br. 8.) And that was disclosed on January 14, 2008.⁷

Plaintiffs also argue that March 30, 2008 is a “corrective disclosure” date because that was the first time the ENHANCE results were presented in a scientific forum and physicians could appreciate the “clinical significance” of the trial. (Pl. Br. 17, 33, 35, 40.) But once Defendants disclosed the very facts they allegedly knew and withheld, additional negative information about the trial was within the portfolio of risks assumed by shareholders. As a matter of law, only an

⁷ Plaintiffs also do not show that Merck withheld the detailed ENHANCE data presented by Dr. Kastelein and other independent scientists on March 30, 2008. (Berger Decl., Ex. 9 at 1432-33.) To the contrary, Plaintiffs emphasize that “a full assessment of the study results [was] not even possible” as of January 17, 2008 because Dr. Kastelein had not completed the analyses, that the “ENHANCE baseline IMT and LDL values changed” between January and March 2008, and that the final data quality statistics were “three times as good” as Dr. Kastelein had assumed. (Pl. Br. 35-36, 25; Pl. SOF ¶¶ 137, 227; Berger Decl., Ex. 157 at 52-54.)

economic loss caused by disclosure of the alleged fraud can show loss causation. *See Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 346 (2005) (“fraudulent conduct [must] proximately cause[] the plaintiff’s economic loss”); *Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 173 (3d Cir. 2001) (plaintiff must prove that a “fraudulent misrepresentation actually caused the loss suffered”); *Semerenko v. Cendant Corp.*, 223 F.3d 165, 184-86 (3d Cir. 2000) (stock price must have “dropped in response to disclosure of the alleged misrepresentations”).

That Merck’s stock price declined by 15% on March 31 also does not show that the alleged fraud was not “fully cured” by the January 14 disclosure. (Pl. Br. 37.) Economic loss, or damages, is a separate element from loss causation. *See Dura*, 544 U.S. at 341-42; 15 U.S.C. § 78u-4(b)(4). The question on this motion is whether the economic loss on March 31 was *caused* by the alleged fraud. *See D.E.&J. Ltd. Partnership v. Conaway*, 133 F. App’x 994, 1000-01 (6th Cir. 2005) (“[T]he observation that a stock price dropped on a particular day . . . is not the same as an allegation that a defendant’s fraud caused the loss.”); *In re Omnicom Grp., Inc. Sec. Litig.*, 541 F. Supp. 2d 546, 554 (S.D.N.Y. 2008), *aff’d*, 597 F.3d 501 (2d Cir. 2010) (citing *In re Merck & Co., Inc., Sec. Litig.*, 432 F.3d 261, 270 (3d Cir. 2005)) (“It is clear that a characterization of previously disclosed facts can cause a loss, just not one attributable to the alleged fraud.”).

IV.

DEFENDANTS DID NOT UNDERMINE THEIR JANUARY 14, 2008 DISCLOSURE

In their opposition brief, Plaintiffs raise three new statements which, they claim, undermined the January 14 disclosure. Those statements, however, did not suggest that the ENHANCE trial had not failed:

- Plaintiffs quote Merck's then-General Counsel, Kenneth Frazier, as saying at a February 5, 2008 industry conference: "[W]e really feel that the ENHANCE data that has been put into the public sphere has been mischaracterized," that "Vytorin and Zetia remain fundamentally important therapeutic options for patients who need to lower their LDL," and "we believe that when the data is fully before [prescribing] physicians, particularly after the ACC presentation in March, that the physicians will also reach that conclusion." (Pl. Br. 13; Berger Decl., Ex. 206 at 2-3.) Plaintiffs do not challenge Merck's recitation of its subjective beliefs, or the objective evidence that Vytorin is highly effective in reducing LDL cholesterol. And, in 2009, after reviewing all of the ENHANCE data, the FDA confirmed that Vytorin remains an important option for patients who need to lower their LDL cholesterol. (Gordon Aff., Ex. 8.)
- Plaintiffs quote Schering-Plough's former CEO, Fred Hassan, as stating on January 17, 2008 that it was "very early to make too many judgments and decisions because the data isn't all out yet" – implying that "the data" referred to the ENHANCE data presented in March 2008. (Pl. Br. 27.) Plaintiffs fail to mention that the very next quotation attributed to Mr. Hassan stated: "You really have to look at the totality of the data, *not just an individual trial*." (Berger Decl., Ex. 187) (emphasis added). Thus, Mr. Hassan's reference to "the data" meant data from trials other than the individual ENHANCE trial – including three outcomes trials for Vytorin. Indeed, just two days earlier, the ACC and AHA had made substantially similar statements that "major clinical decisions [should] not be made on the basis of the ENHANCE study alone," and that "[c]onclusions should not be made until the three large clinical-outcome trials are presented within the next two to three years." (Gordon Aff., Exs. 18-19.)

- Finally, Plaintiffs quote Merck CFO, Peter Kellogg, as stating at a March 17, 2008 healthcare conference: “[P]eople who go to ACC will learn important new information on ENHANCE . . . because in fact I don’t think the full results of the trial have been published and so . . . I think the full data set with all of the subset analysis and different perspectives that go with it would be important.” (Pl. Br. 14.) Again, Plaintiffs conflate disclosure of the alleged fraud with the disclosure of detailed analyses of the ENHANCE results. Certainly, this statement did not contradict the disclosure that Vytorin had failed to beat Zocor on the primary and key secondary endpoints.

The Third Circuit’s decision in *Oran v. Stafford*, 226 F.3d 275 (3d Cir. 2000) is instructive. In *Oran*, plaintiffs similarly attributed a lack of stock price decline after disclosure of adverse test results to “spinning” and “down-playing” of the data. In that case, defendants characterized the data as “limited,” “inconclusive” and requiring “additional scientific investigation” (despite its “important implications”), but the Third Circuit dismissed the case because nothing defendants said was inaccurate. *Id.* at 283. The same is true here.⁸

⁸ *Alaska Elec. Pension Fund v. Pharmacia Corp.*, 554 F.3d 342 (3d Cir. 2009), also supports Merck’s position. There, the court closed the class period when a newspaper article first questioned the trial sponsor’s good faith, as that is when “investors should have known that there was a possibility that defendants’ claims were false.” *Id.* at 351 n.11. The court refused to extend the class period to the date when a medical journal reported new information – causing Pharmacia’s stock price to decline further – since the new information was “different in only degree, and not in kind.” *Id.* at 346, 351 & n.11. The court did not close the class period earlier than the news article first indicating a “possibility of fraud” because Pharmacia misrepresented its study as a *success* at a time when there was no reason for the public to suspect that “anything untoward had occurred.” *Id.* at 349-51. Here, by contrast, Plaintiffs allege that Merck’s disclosure of the *failure* of the ENHANCE trial on January 14, 2008 “shocked the market,” prompted physicians to conclude that Vytorin should not be used as first-line therapy, and led public officials to openly question Defendants’ conduct. (Gordon Aff., Ex. 1 ¶¶ 13, 218-222, 226-31; Exs. 26-28.)

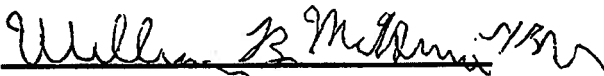
Conclusion

For the foregoing reasons, Defendants' motion for summary judgment should be granted and the Complaint should be dismissed, with prejudice.

Dated: May 18, 2012

Respectfully submitted,

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